

## **Remarks**

New Claims 13 to 22 remain pending in this application. Original Claims 1 to 12 have been cancelled and substituted with new Claims 13 to 22. Applicants submit that no new matter has been added in the new claims. Applicant(s) request the Examiner to reconsider the rejections based on the following:

### **Drawing**

Figure 1 has been replaced. The Examiner has indicated in the office action that Figure 1 does not comply with the MPEP 608.02 (u) (1). Applicants assume that the Examiner wanted amendments to comply with 37 CFR § 1.84 (u) (1). Figure 1 has been amended to comply with 37 CFR § 1.84 (u) (1). Examiner has further stated in the office action that the drawing is objected to because in Figure c, the hidden lines to illustrate the channel length. Applicants submit that Figure c does not have any hidden lines. Therefore, the Applicants are not sure what the Examiner is objecting to.

### **Specification**

Applicants submit that a new Abstract has been written to comply with the word limitations.

### **Claim Objection**

Claim 4 has been objected to due to a parenthetical information. Claim 4 has been deleted, therefore this objection has been rendered moot.

### **Rejection under 35 U.S.C § 103**

Claims 1-4, 5, 6-12 have been rejected under 35 USC 103(a) as being unpatentable over Garcia (4,637,403) in view of Smart et al. (US 2002/0137998) and Mauze et al.

The Examiner has indicated that it would be obvious to modify the needle of Garcia as shown by the Smart or Mauze. As the Examiner is aware, to establish a prima facia case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the references or combine the references. Second, there must be a reasonable

expectation of success. Finally, the prior art reference must teach or suggest all the claim limitation. Additionally, the teachings or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not come from the Applicant's disclosure.

As the Examiner has correctly indicated, the Garcia reference does not disclose a channel open to the outside along a longitudinal extension of the capillary structure. Applicants submit that it is not obvious to replace the needle of Garcia by the needle taught in Smart or Mauze since the Garcia reference teaches away from using an open needle and would result in substantial modification of the Garcia system.

Applicants submit that the Garcia reference discloses a hand held system for measuring blood glucose levels. As shown in Figure 4, the system utilizes a needle (90) to pierce the skin and draw the blood out from under the surface of the skin. As described in detail in Column 7, lines 40 to 45, blood is drawn into the probe area with the help of a vacuum. The Garcia reference also discloses a motivation to retract the capillary structure slightly to allow fluid collection. Applicants respectfully submit that that the capillary structure disclosed in the Garcia reference is a closed channel.

As discussed above, Garcia reference discloses drawing blood to a test area with the help of a closed channel. As shown in Figures, the blood is drawn from underneath the skin when the needle is inserted inside the skin. In one of the embodiment, Figure 9, the blood is drawn from the surface of the skin. However, to withdraw the blood from the surface of the skin, the lancing needle is completely withdrawn and then the blood is drawn through a tube using capillary action.

As contemplated by Gracia, the blood is collected from under the surface of the skin, by applying or creating vacuum on the side of the needle such that blood is sucked to the testing area from the tip of the needle. Therefore, one of the basic principle on which Garcia operates is drawing the blood from under the skin by creating a vacuum along the sides of the needle. As mentioned above, where blood is drawn from the surface of the skin, Garcia contemplates withdrawing the needle before drawing any blood. It does not teach, withdrawing blood from the surface of the skin when a needle is inserted or partially inserted into the skin. As described in Column 12, lines 19 to 25 in order to collect the blood, the needle is retracted halfway to

allow the blood to collect and the blood is then drawn into the teat area by a vacuum generated in the device. As clearly shown in Figures 11 and 12, the Gracia reference contemplates withdrawing blood from underneath the skin and not from the surface of the skin or the side of the skin. In addition, there is no teaching in the Gracia reference to withdraw blood from both underneath the skin and from the surface of the skin.

As seen from the above, an ordinary person skilled in the art would not think of replacing the closed capillary as disclosed in the Garcia reference by an open capillary, since such modification would render the Gracia system inoperable. As one knowledgeable in the art is aware blood from a closed capillary structure can be drawn from underneath the skin and not from the side of the skin, since the opening to draw blood in a closed channel is towards the tip of the needle. Applicants further submit that if the needle with a closed channel in the Garcia reference is substituted with a needle with an open channel, the vacuum applied to draw the blood would not work. In other words, it is not possible to apply vacuum to a system with an open channel since the open portion above the skin would create a vent and no vacuum would be effective. Therefore, if one were to substitute the needle in the Gracia system with the needle as taught in the Smart reference or the Mauze reference, the Garcia system would not work for its intended purpose and would require substantial modification of the Garcia system.

In view of the above, Applicants request the Examiner to withdraw the rejections under 35 USC 103 (a).

### Conclusion

Applicants have filed a complete response to the outstanding office action and only allowable claims remain pending in this application. In view of the above, Applicant(s) request the Examiner to withdraw all rejections. If a personal conversation will expedite the prosecution of this application, the Examiner is requested to call the undersigned at (317) 521-2851.

The Examiner is hereby authorized to charge Deposit Account No. 02-2958 for any fees associated with the filing of this Amendment. A duplicate copy of this sheet is enclosed.

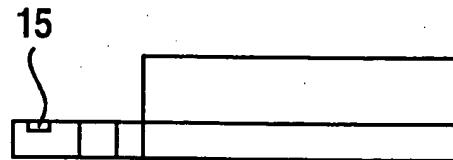
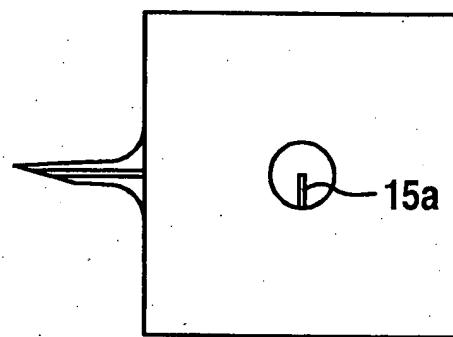
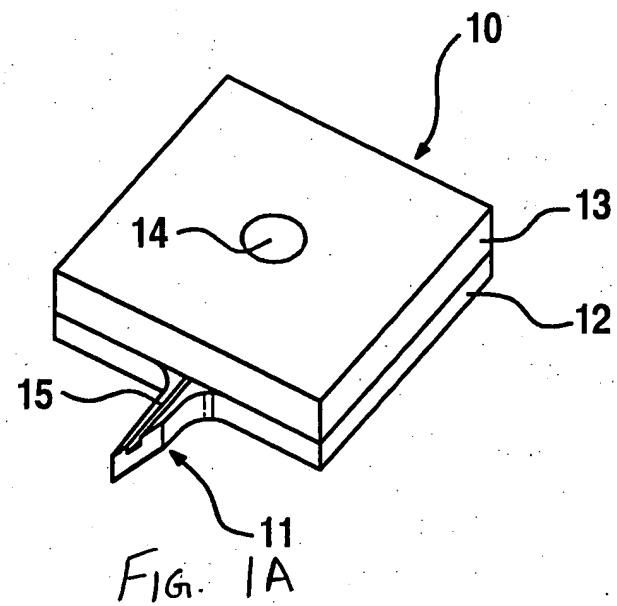
Respectfully submitted,



Date: December 05, 03

Sujatha Subramaniam, Reg. No.48,739  
Roche Diagnostics Corporation  
9115 Hague Road, Bldg. D  
Indianapolis, IN 46250-0457  
Telephone No.: (317) 521-2851  
Facsimile No.: (317) 521-2883

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**CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8)**

Applicant(s): Effenhauser et al.

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**RDID 01056 US**Serial No.  
09/943,080Filing Date  
August 30, 2001Examiner  
WingoodGroup Art Unit  
3736

Invention: System for withdrawing small amounts of body fluid



I hereby certify that this **Amendment and Request for Extension of Time**  
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